

**REMARKS**

Claims 1-9 and 21-37 remain pending. Applicants thank the Examiner for the remarks and withdrawing several of the rejections. Applicants have amended claims 1, 21, and 30 to further define the invention. Applicants submit that support for these amendments can be found in Example 2 on page 12 of the Application and that no new matter was added.

**35 U.S.C. § 112 Rejections**

On page 2 of the Office Action notes that claims 8-9 and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, but on page 3, the Office Action notes that the rejections to these claims were overcome. Thus, Applicants believe that claims 21-29 remain rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants traverse these rejections.

Applicants reiterate their remarks from the previous response. The Office Action alleges that the phrase “free of a bulking agent” is indefinite. Applicants respectfully disagree and traverse this rejection. As made clear by the Federal Circuit, the claims must be read in light the of the specification as it is the best single guide to the meaning of a disputed claim. *Phillips v AWH Corp.*, 415 Fed.3d 1303 Fed. Cir.2005, cert denied 2006 US Lexus 1154 (Feb. 21, 2006) Applicants’ specification states on page 6 – page 7:

As is known to one of skill in the art, a carrier and /or bulking agent is an inert substance in which or on to which the active drug ingredient(s) and excipient(s) if present are dispersed. When the formulations of the present invention utilize HFA 227 as the propellant, it has been surprisingly found that a carrier is not necessary. Accordingly there is disclosed a metered dose inhaler containing an aerosol suspension formulation for inhalation, said aerosol suspension formulation for inhalation comprising: an effective amount of mometasone furoate and HFA 227, wherein the formulation is substantially free of a carrier. The processes for producing the formulations of the present invention preferably utilize HFA 227 or HFA 134a, or a combination thereof, in combination with mometasone furoate and dry powder surfactant.

In light of the specification, it is unclear to the Applicants why the Office Action would conclude that the propellant, specifically HFA 227, is encompassed by the term “bulking agent”. The specification clearly distinguishes the terms “propellant” and “bulking agent”. The specification states at page 6, lines 12-13, “the propellant serves as a vehicle for both the active ingredients and excipients.” The specification separately defines a bulking agent at page 6, line 23 to page 7, line 1 as “an inert substance in which or on to which the active drug ingredient(s) and excipient(s) if present are dispersed.” The specification then goes on to distinguish HFA 227 from a bulking agent. Applicants submit that bulking agent is clearly defined in the specification.

Further, the PTO guidelines do not support the present rejection. M.P.E.P. §2173.02 clearly states that “the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available,” and that the definiteness of claim language must be analyzed in light of “[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.” Applicants submit that a worker skilled in the art would readily appreciate that HFA 227 is not a bulking agent as that term is used in the present application. Accordingly, a skilled worker would not regard the language “free of a bulking agent” as indefinite. Applicants therefore respectfully request reconsideration and withdrawal of this §112, second paragraph rejection.

Claims 1, 6-9, 21, 26, 28-30 and 36-37 are rejected under § 102 as being anticipated by Fassberg, US5474759. Claims 21-26, 28-29, 31-34 and 36-37 are rejected under § 102 as being anticipated by Berry, US6068832. Claims 1-9 and 21-37 stand rejected under 35 U.S.C. § 103(a). Applicants traverse all of these rejections. Applicants note that the Office Action does not appear to give weight for examination purposes to the requirement that the formulation be free of a carrier. Applicants submit that the amended claims are patentable over the cited references and respectfully request withdrawal of the rejections.

Based on the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance and request favorable consideration.

Respectfully submitted,



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